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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,384	02/21/2007	Wonrack Choi	930086-2026	9008

7590 06/23/2009  
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New York, NY 10151

EXAMINER
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HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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06/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,384	<b>Applicant(s)</b> CHOI ET AL.	
	<b>Examiner</b> San-ming Hui	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,9 and 10 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendments filed May 15, 2009 have been entered.

Claims 3-5 are cancelled. Claims 6-12 have been added.

Claims 11-12 are withdrawn as they are directed to non-elected invention.

The outstanding rejection under 35 USC 112 has been withdrawn in view of the amendments of the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 250 852 ('852).

'852 teaches a composition comprising ursolic acid can be isolated from apple skin (See [0001]). Therefore, apple contains ursolic acid, which is encompassed by the claims as one of the herein claimed triterpene compounds.

The herein claimed intended use does not lend any patentable weight to claims that are directed to composition. Apple is considered as food item. Therefore, all of the claim limitations are met.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,948,460 ('460).

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'460 teaches ursolic acid used in food as an emulsifying agent (see the abstract, col. 2, lines 38-40 and claim 1).

The examiner notes that the composition above containing water, which is a pharmaceutically acceptable carrier.

Claims 1-2, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,606,911 ('911).

'911 teaches a composition comprising oleanolic acid or hederagenin (See claims 1-4, also col. 8, example 4, and col. 9, example 5).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over '911 as applied to claims 1-2 and 9 and in further view of Merck Index, 11<sup>th</sup> ed., 1989, pages 901 and 1366.

'911 teaches a composition comprising ursolic acid, oleanolic acid, or hederagenin (See claims 1-4, also col. 8, example 4, and col. 9, example 5). '911 teaches the terpene compounds are useful in treating tooth caries (See abstract for

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example). '911 teaches the excipients as lactose, HPMC, magnesium stearate, Calcium HPO<sub>4</sub>, water (See col. 7, lines 22-35).

'911 does not expressly teach the use of all three terpene compounds (i.e., ursolic acid, oleanolic acid, and hederagenin) together. '911 does not expressly teach mannitol and sodium phosphate dibasic as one of the excipients in the composition.

Merck Index teaches Mannitol as a commonly used excipient and Sodium phosphate dibasic is a known to be useful as buffering agent (See monographs 5629 and 8612).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate mannitol and sodium phosphate dibasic into the composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate all three of the herein claimed terpene compounds into the composition.

One of ordinary skill in the art would have been motivated to incorporate mannitol and sodium phosphate dibasic into the composition since employing the well-known excipients in the composition is reasonably expected to be useful. The examiner notes that similar excipients are used in the composition of '911 (i.e., calcium phosphate and lactose). One of ordinary skill in the art would have been motivated to incorporate all three of the herein claimed terpene compounds into the composition since all of the individual terpene compound is individually well-known for treating tooth caries. It flows logically to combine all three terpene compounds to form a fourth composition useful for the very same purpose (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)).

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui  
Primary Examiner  
Art Unit 1617

/San-ming Hui/  
Primary Examiner, Art Unit 1617